

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOLOGIC, INC. and CYTYC SURGICAL
PRODUCTS, LLC.

Plaintiffs.

V.

MINERVA SURGICAL, INC.,

Defendant.

C.A. No. 15-1031-SLR

JURY TRIAL DEMANDED

REDACTED PUBLIC VERSION

**DEFENDANT MINERVA SURGICAL, INC.'S ANSWER TO HOLOGIC, INC.'S AND
CYTYC SURGICAL PRODUCTS, LLC'S SECOND AMENDED COMPLAINT FOR
INFRINGEMENT AND COUNTERCLAIMS**

Defendant Minerva Surgical, Inc. (“Minerva”), by and through its undersigned attorneys, respectively submits this Answer to the Second Amended Complaint for Patent Infringement (“SAC”) (D.I. 70) filed by Plaintiffs Hologic, Inc. (“Hologic”) and Cytac Surgical Products, LLC (“Cytac”) (collectively, “Plaintiffs”) and Counterclaims against Plaintiffs, as follows:

NATURE OF THE ACTION

1. Minerva admits that this action involves Plaintiffs’ allegations that Minerva infringes U.S. Patent Nos. 6,872,183 (“the ’183 patent”), 8,998,898 (“the ’898 patent”), 9,095,348 (“the ’348 patent), and 9,247,989 (“the ’989 patent”) (collectively “the Patents-in-Suit”).

THE PARTIES

2. Minerva admits only that, upon information and belief, Hologic is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752. Minerva is without knowledge or

information sufficient to form a belief as to the truth of the remaining allegations of paragraph 2 of the SAC, and accordingly denies the same.

3. Minerva admits only that, upon information and belief, Cytoc is a limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752. Minerva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 3 of the SAC, and accordingly denies the same.

4. Minerva is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the SAC, and accordingly denies the same.

5. Minerva admits that it is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 101 Saginaw Drive, Redwood City, CA, 94063.

JURISDICTION AND VENUE

6. Minerva admits that the SAC purports to set forth a claim for patent infringement arising under the Patent Laws of the United States, Title 35 of the United States Code. Minerva further admits that the SAC purports to set forth claims for unfair competition arising under the Lanham Act, 15 U.S.C. § 1051 *et seq.*, and the law of the State of Delaware. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 6 of the SAC.

7. Minerva admits that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338, and 15 U.S.C. §§ 1121(a) and 1125(a). Minerva also admits that this Court has jurisdiction over the state law claims asserted in the SAC pursuant to 28 U.S.C. § 1367, as the state law claims arise from the same common nucleus of operative facts as the federal claims.

8. Minerva admits that this Court has personal jurisdiction over Minerva as a Delaware corporation. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 8 of the SAC.

9. Minerva admits that venue is proper in this District under §§ 1391 and 1400(b) because Minerva is a Delaware corporation, but denies that this is an appropriate or convenient forum for this dispute. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 9 of the SAC.

BACKGROUND

10. Minerva is without knowledge or information sufficient to for a belief as to the truth of the allegations of paragraph 10 of the SAC, and accordingly denies the same.

11. Minerva is without knowledge or information sufficient to for a belief as to the truth of the allegations of paragraph 11 of the SAC, and accordingly denies the same.

12. Minerva is without knowledge or information sufficient to for a belief as to the truth of the allegations of paragraph 12 of the SAC, and accordingly denies the same.

13. Minerva is without knowledge or information sufficient to for a belief as to the truth of the allegations of paragraph 13 of the SAC, and accordingly denies the same.

14. Minerva admits that Exhibit A of the SAC purports to be a copy of the Minerva Endometrial Ablation System Operator's manual. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 14 of the SAC.

15. Minerva is without knowledge or information sufficient to for a belief as to the truth of the allegations of paragraph 15 of the SAC, and accordingly denies the same.

16. Minerva denies all allegations in paragraph 16 of the SAC.

17. Minerva denies all allegations in paragraph 17 of the SAC.

18. Minerva denies all allegations in paragraph 18 of the SAC.

19. Minerva denies all allegations in paragraph 19 of the SAC.

20. Minerva admits that Dr. James Mirabile has a talk radio show on KCMO, 710 AM and 103.7 FM in the Kansas City area and on September 19, 2015 Minerva's Vice President, Eugene Skalnyi, participated in the show to discuss Minerva's Endometrial Ablation System. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 20 of the SAC.

21. Minerva admits that a podcast of the radio show is shared with physicians. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 21 of the SAC.

22. Minerva denies all allegations in paragraph 22 of the SAC.

23. Minerva denies all allegations in paragraph 23 of the SAC.

24. Minerva denies all allegations in paragraph 24 of the SAC.

25. Minerva admits that it provides an Operator's Manual for the Endometrial Ablation System to its physician customers and at the beginning of the Operator's Manual it states "READ ALL INSTRUCTIONS, CAUTIONS AND WARNINGS PRIOR TO USE. FAILURE TO FOLLOW ANY INSTRUCTIONS OR TO HEED ANY WARNINGS OR PRECAUTIONS COULD RESULT IN SERIOUS PATIENT INJURY." Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 25 of the SAC.

COUNT I
(Alleged Infringement of the '183 Patent)

26. Minerva incorporates by reference the above paragraphs of this Answer.

27. Minerva admits that on its face the '183 patent entitled "System and Method for Detecting Perforations in a Body Cavity," was issued on March 29, 2005 to Russel M. Sampson,

Mike O'Hara, Csaba Truckai, and Dean T. Miller. Minerva admits that Exhibit B of the SAC purports to be a true and correct copy of the '183 patent. Minerva denies any and all remaining allegations in paragraph 27 of the SAC.

28. Minerva admits only that, upon information and belief, Cytac claims to have assigned the '183 patent to Hologic on January 15, 2016. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 28 of the SAC, and on that basis, denies them.

29. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 of the SAC, and on that basis, denies them.

30. Minerva admits that it had knowledge of the '183 patent prior to the filing of the original Complaint. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 30 of the SAC.

31. Minerva admits that it had knowledge of the NovaSure® system. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 31 of the SAC.

32. Minerva denies all allegations in paragraph 32 of the SAC.

33. Minerva denies all allegations in paragraph 33 of the SAC.

34. Minerva denies all allegations in paragraph 34 of the SAC.

35. Minerva denies all allegations in paragraph 35 of the SAC.

36. Minerva denies all allegations in paragraph 36 of the SAC.

COUNT II
(Alleged Infringement of the '898 Patent)

37. Minerva incorporates by reference the above paragraphs of this Answer.

38. Minerva admits that Plaintiffs purport that the '898 patent entitled "Moisture Transport System for Contact Electrocoagulation," was issued on April 7, 2005 to Csaba Truckai, Russel M. Sampson, Stephanie Squarcia, Alfonso L. Ramirez, Estela Hilario, and David C. Auth. Minerva admits that Exhibit C of the SAC purports to be a true and correct copy of the '898 patent. Minerva denies any and all remaining allegations in paragraph 38 of the SAC.

39. Minerva admits only that, upon information and belief, Cytac claims it assigned the '898 patent to Hologic on January 15, 2016. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 39 of the SAC, and on that basis, denies them.

40. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 40 of the SAC, and on that basis, denies them.

41. Minerva admits that it had knowledge of the '898 patent prior to the filing of the original Complaint. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 41 of the SAC.

42. Minerva admits that it had knowledge of the NovaSure® system. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 42 of the SAC.

43. Minerva denies all allegations in paragraph 43 of the SAC.

44. Minerva denies all allegations in paragraph 44 of the SAC.

45. Minerva denies all allegations in paragraph 45 of the SAC.

46. Minerva denies all allegations in paragraph 46 of the SAC.

47. Minerva denies all allegations in paragraph 47 of the SAC.

COUNT III
(Alleged Infringement of the '348 Patent)

48. Minerva incorporates by reference the above paragraphs of this Answer.

49. Minerva admits that Plaintiffs purport that the '348 patent entitled "Moisture Transport System for Contact Electrocoagulation," was issued on August 5, 2015 to Csaba Truckai, Russel M. Sampson, Stephanie Squarcia, Alfonso L. Ramirez, and Estela Hilario. Minerva admits that Exhibit D of the SAC purports to be a true and correct copy of the '348 patent. Minerva denies any and all remaining allegations in paragraph 49 of the SAC.

50. Minerva admits only that, upon information and belief, Cytac claims to have assigned the '348 patent to Hologic on January 15, 2016. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 50 of the SAC, and on that basis, denies them.

51. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 51 of the SAC, and on that basis, denies them.

52. Minerva admits that it had knowledge of the '348 patent prior to the filing of the original Complaint. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 52 of the SAC.

53. Minerva admits that it had knowledge of the NovaSure® system. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 53 of the SAC.

54. Minerva denies all allegations in paragraph 54 of the SAC.

55. Minerva denies all allegations in paragraph 55 of the SAC.

56. Minerva denies all allegations in paragraph 56 of the SAC.

57. Minerva denies all allegations in paragraph 57 of the SAC.

58. Minerva denies all allegations in paragraph 58 of the SAC.

COUNT IV
(Alleged Unfair Competition Under 15 U.S.C. § 1125(a))

59. Minerva incorporates by reference the above paragraphs of this Answer.

60. Minerva denies all allegations in paragraph 60 of the SAC.

61. Minerva admits that Minerva markets and/or sells its Endometrial Ablation System in the United States and travels in interstate commerce. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 61 of the SAC.

62. Minerva denies all allegations in paragraph 62 of the SAC.

63. Minerva denies all allegations in paragraph 63 of the SAC.

64. Minerva denies all allegations in paragraph 64 of the SAC.

65. Minerva denies all allegations in paragraph 65 of the SAC.

66. Minerva denies all allegations in paragraph 66 of the SAC.

67. Minerva denies all allegations in paragraph 67 of the SAC.

COUNT V
(Alleged Deceptive Trade Practice Under 6 Del. C. § 2532)

68. Minerva incorporates by reference the above paragraphs of this Answer.

69. Minerva denies all allegations in paragraph 69 of the SAC.

70. Minerva denies all allegations in paragraph 70 of the SAC.

71. Minerva denies all allegations in paragraph 71 of the SAC.

72. Minerva denies all allegations in paragraph 72 of the SAC.

73. Minerva denies all allegations in paragraph 73 of the SAC.

74. Minerva denies all allegations in paragraph 74 of the SAC.

75. Minerva denies all allegations in paragraph 75 of the SAC.

76. Minerva denies all allegations in paragraph 76 of the SAC.

77. Minerva denies all allegations in paragraph 77 of the SAC.

COUNT VI
(Alleged Unfair Competition–Delaware Common Law)

78. Minerva incorporates by reference the above paragraphs of this Answer.

79. Minerva denies all allegations in paragraph 79 of the SAC.

80. Minerva denies all allegations in paragraph 80 of the SAC.

81. Minerva denies all allegations in paragraph 81 of the SAC.

82. Minerva denies all allegations in paragraph 82 of the SAC.

83. Minerva denies all allegations in paragraph 83 of the SAC.

84. Minerva denies all allegations in paragraph 84 of the SAC.

85. Minerva denies all allegations in paragraph 85 of the SAC.

86. Minerva denies all allegations in paragraph 86 of the SAC.

87. Minerva denies all allegations in paragraph 87 of the SAC.

COUNT VII
(Alleged Tortious Interference With A Business Relationship–Delaware Common Law)

88. Minerva incorporates by reference the above paragraphs of this Answer.

89. Minerva denies all allegations in paragraph 89 of the SAC.

90. Minerva denies all allegations in paragraph 90 of the SAC.

91. Minerva denies all allegations in paragraph 91 of the SAC.

92. Minerva denies all allegations in paragraph 92 of the SAC.

93. Minerva denies all allegations in paragraph 93 of the SAC.

94. Minerva denies all allegations in paragraph 94 of the SAC.

95. Minerva denies all allegations in paragraph 95 of the SAC.

96. Minerva denies all allegations in paragraph 96 of the SAC.

97. Minerva denies all allegations in paragraph 97 of the SAC.

COUNT VIII
(Alleged Infringement of the '989 Patent)

98. Minerva incorporates by reference the above paragraphs of this Answer.

99. Minerva admits that on its face the '989 patent entitled "Moisture Transport System for Contact Electrocoagulation," was issued on February 2, 2016 to Csaba Truckai. Minerva admits that Exhibit H of the SAC purports to be a true and correct copy of the '989 patent. Minerva denies any and all remaining allegations in paragraph 99 of the SAC.

100. Minerva admits that Cytac purports to be the assignee and lawful owner of all right, title, and interest in and to the '989 patent. Minerva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 100 of the SAC, and on that basis, denies them.

101. Minerva admits that it had knowledge of the '989 patent prior to the filing of the SAC. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 101 of the SAC.

102. Minerva admits that it had knowledge of the NovaSure® system. Except as expressly admitted, Minerva denies any and all remaining allegations in paragraph 102 of the SAC.

103. Minerva denies all allegations in paragraph 103 of the SAC.

104. Minerva denies all allegations in paragraph 104 of the SAC.

105. Minerva denies all allegations in paragraph 105 of the SAC.

106. Minerva denies all allegations in paragraph 106 of the SAC.

PRAYER FOR RELIEF

1. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 1.
2. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 2.
3. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 3.
4. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 4.
5. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 5.
6. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 6.
7. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 7.
8. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 8.
9. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 9.
10. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 10.
11. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 11.
12. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 12.
13. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 13.
14. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 14.
15. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 15.
16. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 16.
17. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 17.
18. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 18.
19. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 19.
20. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 20.
21. Minerva denies that Plaintiffs are entitled to the relief request in paragraph 21.

AFFIRMATIVE DEFENSES

In addition to the affirmative defenses described below, subject to its responses above, Minerva specifically reserves all rights to allege additional affirmative defenses that become known through the course of discovery.

FIRST AFFIRMATIVE DEFENSE (Failure to State Claim)

107. The SAC fails to state a claim for which relief can be granted.

SECOND AFFIRMATIVE DEFENSE (Noninfringement)

108. Minerva is not infringing and has not infringed, directly, by inducement, contributorily or in any other way, any claim of the '183, '898, '348, and '989 patents.

THIRD AFFIRMATIVE DEFENSE (Invalidity)

109. One or more asserted claims of the '183, '898, '348, and '989 patents are invalid for failing to meet the conditions for patentability in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112.

FOURTH AFFIRMATIVE DEFENSE (Estoppel)

110. The claims of '183, '898, '348, and '989 patents are and were limited by amendment, the prior art, and/or by the statements made during their prosecution before the U.S. Patent and Trademark Office ("USPTO") such that Plaintiffs are now estopped and/or otherwise precluded from maintaining that such claims of the '183, '898, '348, and '989 patents are of sufficient scope to cover the accused products either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE
(Failure to Mark and Limitation on Damages)

111. Plaintiffs' claim for damages is barred in whole or in part by failure to provide adequate notice under 35 U.S.C. § 287. Any claim for damages for patent infringement is limited to only those damages occurring after the notice of infringement and, in any event, by 35 U.S.C. § 286.

SIXTH AFFIRMATIVE DEFENSE
(No Right to Injunctive Relief)

112. Plaintiffs are not entitled to injunctive relief because any injury to Plaintiffs is not immediate or irreparable, and Plaintiffs have an adequate money remedy for any claim that they can prove.

SEVENTH AFFIRMATIVE DEFENSE
(Safe Harbor)

113. There is no infringement—directly, by inducement, contributorily or in any other way—of any valid claim of the '183, '898, '348, and '989 patents by Minerva for any allegedly infringing activities falling within the safe harbor under 35 U.S.C. § 271(e).

EIGHTH AFFIRMATIVE DEFENSE
(Laches)

114. Plaintiffs' claims against Minerva regarding the '183, '898, '348, and '989 patents are barred, in whole or in part, by 35 U.S.C. § 286 and/or the doctrine of laches.

NINTH AFFIRMATIVE DEFENSE
(Obviousness-Type Double Patenting)

115. The asserted claims of the '348 and '989 patents are subject to the doctrine of obviousness-type double patenting. In order to issue, the asserted claims of the '348 and '989 patents should have been subject to a terminal disclaimer setting their respective expiration date as April 12, 2016.

TENTH AFFIRMATIVE DEFENSE
(Unclean Hands)

116. Plaintiffs' claims are barred by the doctrine of unclean hands, the facts and circumstances of which are generally described in Minerva's counterclaims below, including Plaintiffs filing this lawsuit in bad faith and making false and misleading statements related to Minerva and Minerva's products.

ELEVENTH AFFIRMATIVE DEFENSE
(Lack of Standing)

117. Plaintiff Hologic lacks standing to assert any claims relating to the '183, '898, '348 and '989 patents because it did not have sufficient rights in the asserted patents at the time the suit was filed.

COUNTERCLAIMS

PARTIES

118. Minerva hereby pleads the following counterclaims against Plaintiffs.

119. Minerva is a corporation organized under the laws of Delaware, having its principal place of business at 101 Saginaw Drive, Redwood City, CA, 94063.

120. On information and belief, based on Plaintiffs' allegations, Hologic is a corporation organized and existing under the laws of Delaware with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752 and Cytoc is a limited liability company organized and exiting under the laws of the Commonwealth of Massachusetts with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752.

JURISDICTION AND VENUE

121. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

122. Plaintiffs are subject to personal jurisdiction in this judicial district because Plaintiffs availed themselves of the jurisdiction of this Court and engaged in acts giving rise to this controversy in this district.

123. Venue is appropriate in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

124. Since the company's formation in 2008, Minerva has been dedicated to developing and bringing to market new technology that would significantly advance the treatment of abnormal uterine bleeding ("AUB"). To date, Minerva has raised tens of millions from private investors to fund this singular purpose and, having received FDA clearance in July 27, 2015, Minerva is at a critical inflection point for its survival as it begins to commercialize the technology that has been under development for years.

125. Hologic has been well-aware of Minerva's technology and its work since 2009 and has spent years preparing for Minerva's launch. In anticipation of the entrance of new endometrial ablation technology—the first in 15 years—Hologic prepared and is now executing an anti-competitive, no-holds-barred campaign against Minerva that is designed to stamp-out any competition and to prevent Minerva from gaining any traction in the market whatsoever. In doing so, Hologic has gone too far in employing a host of unfair business practices, including the dissemination of false and misleading statements in the marketplace to customers and prospective customers that were carefully designed to permanently and irreparably harm and malign Minerva, its technology, and its employees.

126. Hologic does so not to protect patients or the physicians that treat them, or to fairly engage on the merits competing products, but to protect its market-share at all costs—NovaSure® generates [REDACTED] for Hologic.

127. As Hologic is well-aware, the FDA-approved clinical studies demonstrate that Minerva is a safe, effective product. Indeed, clinical studies demonstrated the following efficacy rates in comparison to the Objective Performance Criteria (“OPC”) (*i.e.*, combined rates of other endometrial ablation devices approved by FDA) of 66%, which include NovaSure®:

	“Success” (Less than normal bleeding- PBLAC < 75)	Amenorrhea (Zero bleeding)	Adverse Events (>2 Weeks–1 Year)	Recommend to a Friend	Average Procedure Time
Minerva	91.8%	66.4%	0%	99%	3.9 minutes
NovaSure®	77.7%	36%	12%	95%	5 minutes

128. Minerva achieved these significant results by developing new endometrial ablation technology using scientific advancement and innovation as well as by drawing on the years of experience that its founders and executives have in this field—several of whom were the original inventors and developers of the NovaSure® technology. Knowing that Minerva’s technology was a significant advancement and that its business and scientific team were well-respected innovators, Hologic took note of this rising threat more than six years before a single Minerva unit was sold in the market.

129. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

130.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

131. In addition, Hologic has employed a number of business practices designed to unfairly inhibit Minerva's ability to compete in the marketplace, including the dissemination of false and/or misleading statements to customers and prospective customers of Minerva. These unfair business practices began in anticipation of Minerva's entry to the market, and have continued since then.

132. Even before Minerva's system was launched, Hologic began disseminating false and deceptive messages about the safety and technological attributes of Minerva's system. Since then, Hologic has approached and continues to approach physicians and hospital administrators who have used, expressed interest in and/or are potential customers of Minerva's system, with a

false and deceptive message that physicians should not use Minerva's system because the device is unsafe for patients.

a.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

b.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

c.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

d.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

e. On February 15, 2015, Minerva formally demanded that Hologic cease and desist from continuing its misleading campaign and to provide a corrective disclosure to those physicians who had exposed to Hologic's false and misleading statements about Minerva and its system. On February 25, 2016, Hologic denied knowledge of any such false or misleading conduct and did not agree to correct its prior statements.

133. On information and belief, Hologic has made and continues to make false and misleading statements about other aspects of Minerva's system, including that the system (i) is associated with a high number of adverse events (contrary to the findings in Minerva's FDA-approved clinical studies); (ii) is associated with a high number of injuries to patients "all over the country"; and (iii) cannot be used in ablation procedures where the patient must first undergo certain other treatments (*e.g.*, removal of polyps or fibroids).

134. Hologic also presents physicians with misleading information about the efficacy of Hologic's NovaSure® device, including on its product label, in articles/advertising sponsored by Hologic, and in direct communications. Since learning the results of Minerva's clinical trials, including efficacy and amenorrhea rates of 91.8% and 66.4% respectively, Hologic continues to depart from the FDA approved results of the NovaSure® clinical study utilized for FDA approval, by advertising on the NovaSure® website that, "The NovaSure® procedure is effective: For 90% of women, menstrual bleeding is dramatically reduced or stopped." The FDA-approved results state efficacy rates of 77.7% (Success rate) and 36% (Amenorrhea or zero bleeding rate). Hologic also advertises that the hysterectomy rate over the five years following the NovaSure® treatment is less than 3%, when the FDA-approved hysterectomy rate over just three years is 6.3%. Minerva is informed and believes that Hologic has not submitted any supplemental study to the FDA for approval of the improved claims. At the same time, Hologic without basis, mischaracterizes and disparages the results of Minerva's clinical study. In doing so, Hologic is in not only in violation of FDA labeling laws, but is also engaged in deceptive advertising under state law, including the law of Delaware.

FIRST COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '183 Patent)

135. Minerva realleges and incorporates by reference the foregoing paragraphs.

136. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '183 patent.

137. Plaintiffs have charged in the SAC that one or more claims of the '183 patent have been infringed by Minerva.

138. Minerva denies that Minerva has been or is infringing, directly, or indirectly, any of the claims of the '183 patent or otherwise engaging in any wrongdoing with respect to such patent. Minerva further avers that it has not infringed and is not presently infringing, directly or indirectly, any valid or enforceable claims contained in the '183 patent and it is not liable for damages, injunctive or other relief arising from such alleged infringement.

139. There exists an actual and justifiable controversy between Minerva and Plaintiffs as to whether Minerva infringes any claims of the '183 patent. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

140. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that it does not infringe any claims of the '183 patent.

SECOND COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '898 Patent)

141. Minerva realleges and incorporates by reference the foregoing paragraphs.

142. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '898 patent.

143. Plaintiffs have charged in the SAC that one or more claims of the '898 patent have been infringed by Minerva.

144. Minerva denies that Minerva has been or is infringing, directly, or indirectly, any of the claims of the '898 patent or otherwise engaging in any wrongdoing with respect to such patent. Minerva further avers that it has not infringed and is not presently infringing, directly or

indirectly, any valid or enforceable claims contained in the '898 patent and it is not liable for damages, injunctive or other relief arising from such alleged infringement.

145. There exists an actual and justifiable controversy between Minerva and Plaintiffs as to whether Minerva infringes any claims of the '898 patent. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

146. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that it does not infringe any claims of the '898 patent.

**THIRD COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '348 Patent)**

147. Minerva realleges and incorporates by reference the foregoing paragraphs.

148. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '348 patent.

149. Plaintiffs have charged in the SAC that one or more claims of the '348 patent have been infringed by Minerva.

150. Minerva denies that Minerva has been or is infringing, directly, or indirectly, any of the claims of the '348 patent or otherwise engaging in any wrongdoing with respect to such patent. Minerva further avers that it has not infringed and is not presently infringing, directly or indirectly, any valid or enforceable claims contained in the '348 patent and it is not liable for damages, injunctive or other relief arising from such alleged infringement.

151. There exists an actual and justifiable controversy between Minerva and Plaintiffs as to whether Minerva infringes any claims of the '348 patent. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

152. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that it does not infringe any claims of the '348 patent.

FOURTH COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '989 Patent)

153. Minerva realleges and incorporates by reference the foregoing paragraphs.

154. Plaintiffs allege in the SAC that Cytoc is the owner of all rights, title, and interest in the '989 patent.

155. Plaintiffs have charged in the SAC that one or more claims of the '989 patent have been infringed by Minerva.

156. Minerva denies that Minerva has been or is infringing, directly, or indirectly, any of the claims of the '989 patent or otherwise engaging in any wrongdoing with respect to such patent. Minerva further avers that it has not infringed and is not presently infringing, directly or indirectly, any valid or enforceable claims contained in the '989 patent and it is not liable for damages, injunctive or other relief arising from such alleged infringement.

157. There exists an actual and justifiable controversy between Minerva and Plaintiffs as to whether Minerva infringes any claims of the '989 patent. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

158. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that it does not infringe any claims of the '989 patent.

FIFTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '183 Patent)

159. Minerva realleges and incorporates by reference the foregoing paragraphs.

160. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '183 patent.

161. Each and every claim of the '183 patent is invalid for failing to meet and conditions for patentability in Title 35 of the United States Codes, including but not limited to §§ 101, 102, 103, and/or 112.

162. There exists an actual and justiciable controversy between Minerva and Plaintiffs as to whether one or more claims of the '183 patent is invalid. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

163. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that one or more claims of the '183 patent are invalid.

**SIXTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '898 Patent)**

164. Minerva realleges and incorporates by reference the foregoing paragraphs.

165. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '898 patent.

166. Each and every claim of the '183 patent is invalid for failing to meet and conditions for patentability in Title 35 of the United States Codes, including but not limited to §§ 101, 102, 103, and/or 112.

167. There exists an actual and justiciable controversy between Minerva and Plaintiffs as to whether one or more claims of the '898 patent is invalid. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

168. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that one or more claims of the '898 patent are invalid.

**SEVENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '348 Patent)**

169. Minerva realleges and incorporates by reference the foregoing paragraphs.

170. Plaintiffs allege in the SAC that Hologic is the owner of all rights, title, and interest in the '348 patent.

171. Each and every claim of the '348 patent is invalid for failing to meet and conditions for patentability in Title 35 of the United States Codes, including but not limited to §§ 101, 102, 103, and/or 112.

172. There exists an actual and justiciable controversy between Minerva and Plaintiffs as to whether one or more claims of the '348 patent is invalid. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

173. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that one or more claims of the '348 patent are invalid.

EIGHTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '989 Patent)

174. Minerva realleges and incorporates by reference the foregoing paragraphs.

175. Plaintiffs allege in the SAC that Cytac is the owner of all rights, title, and interest in the '989 patent.

176. Each and every claim of the '989 patent is invalid for failing to meet and conditions for patentability in Title 35 of the United States Codes, including but not limited to §§ 101, 102, 103, and/or 112.

177. There exists an actual and justiciable controversy between Minerva and Plaintiffs as to whether one or more claims of the '989 patent is invalid. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

178. Pursuant to 28 U.S.C. §§ 2201 and 2202, Minerva is entitled to a declaratory judgment that one or more claims of the '989 patent are invalid.

NINTH COUNTERCLAIM
(Unfair Competition Under 15 U.S.C. § 1125(a) & (c))

179. Minerva realleges and incorporates by reference the foregoing paragraphs.

180. Hologic has used a false or misleading description of facts in connection with its marketing and sale of the NovaSure® device.

181. Hologic markets and/or sells the NovaSure® device throughout the United States and travels in interstate commerce.

182. Hologic's conduct has caused and continues to cause confusion or mistake, or has deceived and continues to deceive existing and potential Minerva customers about the relative characteristics of the NovaSure® and Minerva devices.

183. Hologic's conduct has caused further harm to Minerva in the form of tarnishment of Minerva, its device and its mark.

184. Hologic's conduct constitutes unfair competition in violation of 15 U.S.C. § 1125(a) and (c).

185. As a result of Hologic's false description of facts, Minerva has suffered and continues to suffer damages, including loss of sales.

186. Hologic's false and misleading description of facts is willful, making this an exceptional case entitling Minerva to recover Hologic's profits of sales of NovaSure®, actual and enhanced damages, and costs Minerva incurred in prosecuting its claims, pursuant to 15 U.S.C. § 1117(a) and (c).

187. Hologic's false and misleading description has caused and will continue to cause irreparable harm to Minerva for which there is no adequate remedy at law, unless the Court enjoins Hologic's false and misleading statements pursuant to 15 U.S.C. § 1116(c).

TENTH COUNTERCLAIM
(Deceptive Trade Practices Under 6 Del. C. § 2532)

188. Minerva realleges and incorporates by reference the foregoing paragraphs.

189. Hologic in the course of its business, has engaged and continues to engage in conduct that disparages the Minerva system, including without limitation, but and through its false and misleading representation that the Minerva system is unsafe [REDACTED]

[REDACTED]

[REDACTED]

190. Hologic in the course of its business, has engaged and continues to engage in conduct that causes a likelihood of confusion or misunderstanding about the Minerva system, including without limitation, but and through its false and misleading representation that the Minerva system is unsafe [REDACTED]

[REDACTED]

191. Hologic in the course of its business, by and through its false and misleading representations of fact, has engaged and continues to engage in deceptive trade practices in violation of 6 Del. C. § 2532, including without limitation, but and through its false and misleading representation that the Minerva system is unsafe [REDACTED]

[REDACTED]

[REDACTED]

192. As a result of Hologic's conduct, Minerva has suffered and continues to suffer damages, including loss of sales.

193. Equity favors enjoining Hologic's conduct pursuant to 6 Del. C. § 2533(a).

194. Hologic's conduct has been and is willful such that Minerva is entitled to its attorneys' fees and costs.

195. Minerva is entitled to damages under Delaware common law thereby entitling Minerva to treble damages under 6 Del. C. § 2533(c).

**ELEVENTH COUNTERCLAIM
(Unfair Competition--Delaware Common Law)**

196. Minerva realleges and incorporates by reference the foregoing paragraphs.

197. Minerva had a reasonable expectancy of entering and continuing valid business relationships with existing and potential customers.

198. Hologic has wrongfully interfered with Minerva's existing and potential business relationships by approaching customers that were using, interested in and/or potential customers of Minerva's system and [REDACTED]

[REDACTED] (ii) making false and misleading statements of fact regarding the contraindications of Minerva's system; (iii) disparaging Minerva's system, Minerva, and its employees; (iv) making false and misleading statements about the efficacy of Hologic's NovaSure® device; and [REDACTED]

199. Hologic has used and continues to use false and/or misleading descriptions of facts in connection with its marketing and/or sale of the NovaSure® system.

200. Hologic's conduct has caused and continues to cause confusion or mistake, or has deceived and continues to deceive existing and potential customers of Minerva about the relative characteristics of the NovaSure® and Minerva devices.

201. Hologic's conduct has caused and continues to be undertaken with the purpose of deceiving customers and appropriating Minerva's business relationships, goodwill, and competitive advantages.

202. Hologic's conduct constitutes unfair competition under the common law, including without limitation by its activities in Delaware.

203. As a result of Hologic's misconduct, Minerva has suffered and continues to suffer economic harm, including loss of sales. As a result of Hologic's misconduct, Hologic has caused and will continue to cause customer confusion or misunderstanding and has caused and will continue to cause damage to Minerva's goodwill with customers and potential customers.

204. Hologic's misconduct has caused and will continue to cause irreparable harm to Minerva for which there is no adequate remedy at law, unless its conduct is enjoined.

TWELFTH COUNTERCLAIM
(Interference with Contract/Business Advantage)

205. Minerva realleges and incorporates by reference the foregoing paragraphs.

206. Minerva had a reasonable expectancy of entering and continuing valid business relationships with existing and prospective customers as well as others, including clinical investigators under contract with Minerva.

207. On information and belief, Hologic had knowledge of Minerva's business relationships and prospective customers as Hologic has been tracking Minerva's activity, including the whereabouts of its sales staff, since before Minerva's system was commercially available and all times since.

208. Hologic has intentionally interfered with Minerva's existing and potential business relationships by approaching customers that were using, interested in and/or potential customers of Minerva's system and (i) making false and misleading statements of fact regarding the safety of Minerva's system, [REDACTED]

[REDACTED] (ii) making false and misleading statements of fact regarding the contraindications of Minerva's system; (iii) disparaging Minerva's system,

Minerva, and its employees; (iv) making false and misleading statements about the efficacy of Hologic's NovaSure® device; and (v) [REDACTED]

209. Hologic, by and through its false and misleading statements and conduct, has engaged and in and continues to engage in wrongful conduct in violation of federal and state law, including 15 U.S.C. § 1125 and 6 Del. C. § 2532.

210. Hologic's conduct constituted tortious interference with a business relationship under the common law, including without limitation its activities in Delaware.

211. As a result of Hologic's intentional interference, Minerva has suffered and continues to suffer economic harm, including loss of sales.

212. Hologic's actions and conduct are willful and undertaken with the purpose of deceiving customers.

213. Hologic's intentional interference has caused and will cause irreparable harm to Minerva for which there is no adequate remedy at law, unless the conduct is enjoined.

**THIRTEENTH COUNTERCLAIM
(Breach of Contract)**

214. Minerva realleges and incorporates by reference the foregoing paragraphs.

215. [REDACTED]

216. [REDACTED]

217. [REDACTED]

218. [REDACTED]

219. [REDACTED]

220. [REDACTED]

**FOURTEENTH COUNTERCLAIM
(Trade Libel)**

221. Minerva realleges and incorporates by reference the foregoing paragraphs.

222. Through systematic communications and misrepresentation made by Plaintiffs, Plaintiffs have intentionally published and perpetuated false and malicious statements about Minerva.

223. Plaintiffs' statements are false and were known by Plaintiffs to be false when made.

224. Plaintiffs have made statements about Minerva willfully, with intent to disparage Minerva, and the products offered for sale by Minerva.

225. Plaintiffs' statements were made with the intent and knowledge that individuals and entities with whom Minerva dealt would cease its business dealings with Minerva.

226. Plaintiffs' conduct has caused, and if allowed to continue will continue to cause, Minerva to suffer substantial irreparable injury, for which there is no adequate remedy at law.

227. Minerva has suffered damages as a result of Plaintiffs' actions, including but not limited to a loss of revenue, profits, goodwill, and future earnings.

JURY DEMAND

Minerva demands a trial by jury on all issues so triable.

REQUEST FOR RELIEF

WHEREFORE, Minerva respectfully requests that the Court enter judgment as follows:

- A. A judgment in favor of Minerva on all of its Counterclaims;
- B. Dismissal of all of Plaintiffs' claims in their entirety with prejudice;
- C. A judgment that Plaintiffs take nothing by their Second Amended Complaint;
- D. A declaration that Minerva does not infringe, directly or indirectly, literally or by the doctrine of equivalents, any valid enforceable claims of the '183, '898, '348, and '989 patents;
- E. A declaration that each and every claim of the '183, '898, '348, and '989 patents is invalid;
- F. Awarding damages to Minerva for tortuously interfering with Minerva's business relationships and for unfairly competing with Minerva under both Federal and Delaware law;

G. Awarding damages to Minerva for breach of contract;

H. An order preliminarily and permanently enjoining Plaintiffs, their affiliates and subsidiaries, and each of their officers, agents, servants and employees and those acting in privity of concert with them, from:

i. Threatening to assert or otherwise attempt to enforce the '183, '898, '348, and '989 patents against Minerva, its customers, suppliers, or anyone in privity with Minerva;

ii. Distributing or using any advertising, promotional material, sales material, solicitations, or mailing (electronic or otherwise), or making any statement to its customers, potential customers or suppliers, which contains an express or implied claim that Minerva has infringed or is infringing the '183, '898, '348, and '989 patents unless and until there is such a judgment of infringement against Minerva;

iii. Using this action or any other lawsuit between any of the parties to this action to solicit business for Plaintiffs;

iv. Soliciting or accepting orders from a customer using the false and or misleading advertising or unfair competitive statements discussed herein, or any other advertising or statements containing similar false or misleading claims;

v. Using false and/or misleading representations or descriptions in commerce that are likely to cause confusion regarding the characteristics of Minerva's accused system;

vi. Using false and/or misleading representations or descriptions in commerce that interfere with or are likely to injure Minerva's business relations;

vii. Unfairly competing with Minerva; and

viii. Committing any acts which are likely to injure Minerva's business reputation.

I. A judgment that this is an “exceptional case” and an award of Minerva’s reasonable attorneys’ fees, expenses, and costs in this action under 35 U.S.C. § 285; and

J. An award of such other relief as the Court may deem appropriate and just under the circumstances.

Respectfully submitted,

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Dated: March 4, 2016

CERTIFICATE OF SERVICE

I, Benjamin J. Schladweiler, hereby certify that on March 4, 2016, I caused the foregoing *Defendant Minerva Surgical, Inc.'s Answer to Hologic, Inc.'s and Cytoc Surgical Products, LLC's Second Amended Complaint for Infringement and Counterclaims* to be served via electronic mail upon the following counsel of record:

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